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MEMO ENDORSED

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2007

Honorable Denise Cote
United States District Court
Southern District of New York
500 Pearl Street, Room 1040
New York, New York 10007

Re: Takeda Pharmaceutical Company Limited et. al. v. Sandoz, Inc.
Civil Case No. 07 CIV 3844 DLC
SSJR File No. 4802-L0001A

Dear Judge Cote:

During the initial pre-trial conference on July 27, 2007, your honor requested a brief letter from Sandoz regarding Sandoz' pending motions and their potential effect on the exclusivity rights of the defendants in the related pioglitazone patent cases.

Sandoz' Motions

Sandoz' first motion is a motion to dismiss counts III-IX of the complaint. These are declaratory judgment counts that do not relate to ANDA infringement under 35 U.S.C. §271(e), and therefore, this motion does not affect any exclusivity rights of other defendants.

Sandoz' second motion is a motion for judgment on the pleadings with respect to counts I and II of the complaint, which relate to two "combination" patents (U.S. Patent Nos. 5,965,584 and 6,329,404). These counts *do* relate to Sandoz' ANDA, and thus, were brought under 35 U.S.C. §271(e). Sandoz has provided Plaintiff and the Court with copies of Sandoz' Patent Certification and the proposed label from its ANDA, evidencing that Sandoz' ANDA does not amount to "artificial infringement" under §271(e). Accordingly, Sandoz submits that the Court has all of the necessary information to render judgment of noninfringement of the combination patents. Such a judgment would trigger any 180-day generic exclusivity period.

Triggering Exclusivity

Plaintiff has asserted the two aforementioned "combination" patents against Mylan, Ranbaxy, Watson (and Sandoz) under 35 U.S.C. § 271(e). It appears

that all of the other defendants filed their ANDAs on the same day. *Takeda Chemical Industries, Ltd. v. Mylan Laboratories, Inc.*, 417 F.Supp.2d 341, 365 (S.D.N.Y. 2006). Accordingly, Mylan, Ranbaxy, and Watson, as the remaining "first-filers," may be eligible for the 180-day period of "multiple applicant" exclusivity to market pioglitazone, presuming they obtain judgments of noninfringement of the two "combination" patents being asserted against them under 35 U.S.C. § 271(e) and the FDA approves their ANDAs. *See Minnesota Mining and Mfg. Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002). *See also* FDA's Guidance Document regarding multiple applicant exclusivity (July 2003), available at http://www.fda.gov/cder/guidance/5710fnl.htm

However, under the law governing ANDAs filed at that time,[1] this exclusivity period begins to run from either: (a) the date Mylan, Ranbaxy, or Watson first begins to sell generic pioglitazone, or (b) the date another generic manufacturer obtains a final ruling, *i.e.*, a ruling from which no appeal has or can be taken, that the relevant patents are invalid or not infringed. *Minnesota Mining and Mfg. Co.*, 289 F.3d at 780; Pub.L. 108-173, Title XI, § 1102(b)(3). The ability of a later ANDA filer to trigger the exclusivity of a first ANDA filer is designed to prevent a first ANDA filer from blocking other generic companies from entering the market simply because the first ANDA filer is involved in protracted litigation. *Minnesota Mining and Mfg. Co.*, 289 F.3d at 780. Once a generic company's exclusivity period has run, it allows other generic companies to enter the market, resulting in a reduction of the market price of the relevant drug. *See, e.g., In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 216 (2nd Cir. 2006).

Accordingly, if Sandoz obtains a judgment of noninfringement, which is not appealed or is affirmed by the Court of Appeals, any 180-day exclusivity period will be triggered. If the 180 days has then run by January 2011 (when the original '777 patent for pioglitazone expires), Sandoz (and other generic companies that have obtained final FDA approval) will be able to market pioglitazone by itself (i.e., for monotherapy). If an exclusivity period is still in place, Sandoz will be prevented from marketing pioglitazone by itself at that time, even though the basic patent will have expired.

Sandoz must promptly serve this letter on all parties to the pioglitazone litigation. Granted. So Ordered. August 6, 2007

Respectfully submitted,

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[1] Today, the statutory framework enumerates both "triggering" and "forfeiture" events for this 180-day exclusivity, modifying the "triggering" framework described above that applies to first-filed ANDAs filed before the statutory amendments of Dec. 8, 2003. *See* 21 U.S.C. §355(j)(5)(D).

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